SEP 14 2006

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K061225

stryker

Endoscopy

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Proprietary Name:	Stryker Disposable Laparoscopic Scissors
Common and Usual Name:	Laparoscopic Scissors
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of the SMDA 1990.

The Stryker Disposable Laparoscopic Scissors are substantially equivalent in terms of safety and effectiveness to currently marketed devices, including the Stryker Multi Cut Scissors (K935237).

The Stryker Disposable Laparoscopic Scissors are composed of an ABS plastic handle, 304 and 420 grade stainless steel, silicon, and medical grade PPSU (Radel). All materials are tested for biocompatibility as any of these materials may come into contact with both the patient and surgeon. The device is distributed sterile and intended for single use only.

The Stryker Disposable Laparoscopic Scissors are intended for cutting, dissecting and performing monopolar electrosurgery during any laparoscopic procedure.

The Stryker Disposable Laparoscopic Scissors are tested to conform to the following voluntary safety and performance standards: ISO 10993-1:2003 Biological Evaluation of Medical Devices, ASTM D4169:2004 Standard Practice for Performance Testing of Shipping Containers and Systems, AAMI HF-18 Electrosurgical Devices, IEC 60601-1:1988 Medical Electrical Equipment: General Requirements for Safety, ISO7741:1986 Instruments for Surgery – Scissors and Shears: General Requirements and Test Methods and EN 552:1994 Sterilization of Medical Devices – Validation and Routine Control of Irradiation.

There are no significant technological or performance differences between the Stryker Disposable Laparoscopic Scissor and the identified predicate devices [Stryker Multi Cut Scissors (K935237)] nor are there any new questions raised regarding safety or effectiveness, therefore, the Stryker Disposable Laparoscopic Scissor is substantially equivalent to the identified predicate devices and surgery systems.

Desiree Mae Crisolo — Date:
Regulatory Affairs Representative

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2006

Stryker Corporation
% Stryker Endoscopy
Ms. Desiree Mae Crisolo
Regulatory Affairs Representative
5900 Optical Court
San Jose, California 95138

Re: K061225
Trade/Device Name: Stryker Disposable Laparoscopic Scissors
Regulation Number: 21 CFR 878.4400
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 21, 2006
Received: August 21, 2006

Dear Ms. Crisolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (K) Number: K061225

Device Name: Stryker Disposable Laparoscopic Scissors

Indications for Use:

The Stryker Disposable Laparoscopic Scissors are intended for cutting, dissecting and performing monopolar electrosurgery during any laparoscopic procedure.

Prescription Use___X___ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061225